IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FOREST LABORATORIES, LLC, FOREST LABORATORIES HOLDINGS, LTD., MERCK KGaA and MERCK PATENT GESELLSCHAFT MIT BESCHRÄNKTER HAFTUNG,	)	
Plaintiffs,	)	C.A. No. 15-272 (GMS)
v.	)	CONSOLIDATED
ACCORD HEALTHCARE INC., et al.	)	
Defendants.	)	

PLAINTIFFS' ANSWERING CLAIM CONSTRUCTION BRIEF

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I. INTRODUCTION

Defendants' proffered claim constructions find no support in the record. Instead, defendants propose constructions that veer far from the ordinary meaning of the claim terms, with no supporting lexicography or disavowal in the specification or prosecution history. Defendants base their proposals primarily on a scattershot of prosecution history citations that, upon examination, simply do not support their suggested constructions. Defendants' constructions also conflict with the understanding of a person of ordinary skill in the art ("POSA"), a necessary perspective essentially ignored in defendants' opening brief ("Def. Br.").

By contrast, plaintiffs' proposed constructions for the disputed claim terms are consistent with the intrinsic record, as well as with the understanding of a POSA, as described in plaintiffs' opening brief ("Pl. Br."). Plaintiffs' proposed constructions should be adopted.

II. THE DISPUTED CLAIM TERMS AND PHRASES

A. "Crystalline" / "Crystalline modification"

Claim Term	Patent/claim	Plaintiffs' Proposed Construction	Defendants' Proposed Construction
"crystalline"	'195 patent, claim 1 '020 patent, claim 1 '921 patent, claims 1, 5, 11, 13 '804 patent, claim 1	Plain meaning/no construction required	Entirely in crystalline form comprising only Form I to XVI, and combinations thereof (as appropriate)
"crystalline modification"	'020 patent, claim 1 '921 patent, claims 1, 5, 11, 13 '804 patent, claim 1	Crystalline form	Construe together with "crystalline"

As discussed in plaintiffs' opening brief, "crystalline" has a well-understood plain and ordinary meaning. Pl. Br. 5-6; Bernstein Decl. ¶¶ 34-36. The use of that term in the patent claims and specification is consistent with that plain and ordinary meaning. Indeed, defendants'

own proposed construction, which simply repeats the term "crystalline" without defining it, confirms that the term must have this well-understood meaning. *See* Pl. Br. 5-6.

As a threshold matter, Defendants fail to defend (or even address) several elements of their proposed construction of the "crystalline" claim terms. First, they offer no explanation for their suggestion that the construction should include the ambiguous phrase "[e]ntirely in crystalline form."[1] Second, defendants fail to explain or even address the similarly vague phrase "as appropriate" in their construction. *See* Pl. Br. 9. Third, defendants do not separately address the construction of "crystalline modification" at all, and do not explain how or why that term should be construed identically to the term "crystalline." As detailed in plaintiffs' opening brief, the intrinsic evidence demonstrates that "crystalline modification" should be construed as "crystalline form." *See, e.g.*, '804 patent, col. 2, ll. 36-38; Pl. Br. 9-10.

Defendants focus their argument on their proposed construction of the "crystalline" claim terms as "comprising only Form I to XVI." *See* Def. Br. 7-11. Specifically, defendants argue that "crystalline" must be limited to Forms I to XVI because these are the only forms that the patent specification expressly discloses. Def. Br. 7. But it "is improper to read limitations from a preferred embodiment described in the specification—even if it is the only embodiment—into the claims absent a clear indication in the intrinsic record that the patentee intended the claims to be so limited." *Braintree Labs., Inc. v. Novel Labs., Inc.*, 749 F.3d 1349, 1355 (Fed. Cir. 2014)

[1] Without elaboration, defendants accuse plaintiffs of arguing that the "crystalline" terms may encompass "a form that is ***not*** crystalline." Def. Br. 7 (emphasis in original). But plaintiffs have never argued that "crystalline" can mean "not crystalline." Moreover, to the extent that this unexplained assertion is intended to justify defendants' inclusion of "entirely in crystalline form" in their proposed construction, it should be rejected. As stated in plaintiffs' opening brief, nothing in the record suggests that an ***infringing product*** must be "entirely" crystalline to fall within the claims of the patents-in-suit, and such a reading would be contrary to the understanding of a POSA. *See* Pl. Br. 6-8. Moreover, as to the portion of a product ***that is crystalline***, it is tautological to define it as "entirely in crystalline form." *See* Pl. Br. 8.

(citation omitted). As shown below, there is no such "clear indication" in the intrinsic evidence here. Indeed, the specification clearly indicates precisely the opposite, emphasizing that "[t]he preferred specific embodiments and examples are . . . to be construed as merely illustrative, and not limitative to the remainder of the disclosure in any way whatsoever." *See, e.g.*, '804 patent, col. 16, ll. 20-22.

Defendants argue that certain claims in the patents-in-suit reference specific forms, such as "crystalline modification IV" in claim 1 of the '804 patent. Def. Br. 7. That is correct. But this fact supports ***plaintiffs'*** position rather than defendants'. Given that both the claims and specification in the patents-in-suit reference certain specific crystalline forms in some instances, and "crystalline" forms more generally in others, it follows that the unmodified term "crystalline" is ***not*** inherently limited to those forms expressly disclosed in the specification or claimed in certain claims. *See, e.g.*, *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005) (en banc) (use of "steel baffles" in a claim "strongly implies that the term 'baffles' does not inherently mean objects made of steel"). *See, e.g.*, '804 patent, col. 2, ll. 39 to col. 3 ll. 19; see also col. 11, ll. 34-36; col. 13, ll. 62-64; col. 14, ll. 29-32; *see also* '195 patent, claims 1-6; '921 patent, claim 1.

Not only does the claim language lack ***any*** support for defendants' proposed limitation of "comprising only Form I to XVI," that proposed limitation is wholly disconnected from the plain meaning of "crystalline," which refers to a solid form in which atoms or molecules are arranged with a three-dimensional long-range order. *See* Pl. Br. 5; Bernstein Decl. ¶¶ 19, 35 (citing Bruno Hancock et al., J. Pharma. Scis., 1997, vol. 86, at 1; A Dictionary of Chemistry 140 (John Daintith Ed., 3rd ed. 1996)); *cf. Pfizer Inc. v. Dr. Reddy's Labs. Ltd.*, C.A. No. 09-943-

LPS, 2011 WL 767849, at *7 (D. Del. Feb. 28, 2011) (construing "crystalline" to mean "a solid form having a long range periodic ordered structure extending in three dimensions").[2]

The law is clear that "[a]bsent lexicography or disavowal, we do not depart from the plain meaning of the claims." *Luminara Worldwide, LLC v. Liown Elecs. Co. Ltd.*, 814 F.3d 1343, 1353 (Fed. Cir. 2016); *see also GE Lighting Sols., LLC v. AgiLight, Inc.*, 750 F.3d 1304, 1309 (Fed. Cir. 2014). This is an "exacting" standard. *Luminara*, 814 F.3d at 1353 (citation omitted). Lexicography requires that "a patentee must 'clearly set forth a definition of the disputed claim term,' and 'clearly express an intent to redefine the term.'" *Id.* (citation omitted). Disavowal requires that "the specification [or prosecution history] make[] clear that the invention does not include a particular feature." *Id.* (citation omitted, alterations in original); *see also Unwired Planet, LLC v. Apple Inc.*, __F.3d__, 2016 WL 3947839, *3 (Fed. Cir. July 22, 2016) ("A disclaimer or disavowal of claim scope must be clear and unmistakable, requiring 'words or expressions of manifest exclusion or restriction' in the intrinsic record." (citation omitted)). Here, defendants fail even to acknowledge this high standard, let alone meet it. None of the language cited by defendants in the patent specification or prosecution history evidences either lexicography or disavowal with respect to "crystalline."

a) The specification does not support defendants' construction

Defendants first point to the statement in the specification that "[t]here is no clear teaching in [prior art U.S. Patent No. 5,532,241] of any alternative route or modification to the

[2] Defendants assert that, under plaintiffs' proposed construction, references to specific forms in the claims "are simply nonsensical." Def. Br. 7. That is not correct. Rather, under plaintiffs' proposed construction, the asserted claims include limitations to specific forms when such limitations are explicitly stated, and contain no such limitations when such limitations are not explicitly stated. There is nothing "nonsensical" about this position.

process which would generate new crystal modifications of [vilazodone] or new solvates or hydrates of [vilazodone] in different crystal modifications." Def. Br. 8 (quoting '921 patent, col. 1, ll. 57-64). But nothing in this discussion about the teachings of a ***prior art patent*** suggests an intention to limit the ***patents-in-suit*** themselves to certain specific crystalline forms. Defendants also cite the specification's proposition that certain crystalline forms "may be of interest to those involved in the development of a suitable dosage form" because of the importance of holding form constant "during clinical and stability studies," and that it is "imperative to assure" that "a single morphological form or some known combination of morphological forms is present." Def. Br. 8 (quoting '921 patent, col. 2, ll. 6-18). Again, this language provides no support for defendants' position. Rather, this general discussion of the value of identifying crystalline forms places no limitations on the meaning of "crystalline."

Defendants also point to the statement in the specification that "the present invention provides" solvates, hydrates and anhydrates of vilazodone "in crystalline modifications and their use." Def. Br. 8 (quoting '921 patent, col. 2, ll. 44-47, 56-59 and col. 3, ll. 1-4). Defendants conclude from this language that "the term 'crystalline' or 'crystalline modifications' refers to the specific solvate, hydrate, and anhydrate polymorphs found in these specific patents." The sentences in question contain no such limitation, however. Indeed, these statements ***contradict*** defendants' argument that "crystalline" should be interpreted as limited to specific crystalline forms, because they refer only generally to solvates, hydrates, and anhydrates ***without*** reference to any specific forms.

Finally, defendants cite to the patent specifications' reference to forms I through XVI as "products of the invention." Def. Br. 8-9 (citing '921 patent, col. 2, ll. 41-43, col. 14, ll. 58-63). Forms I through XVI are undoubtedly products of the invention. But that fact does not mean that

the term "crystalline" is therefore limited to these specific forms. Indeed, "as a general rule claims of a patent are not limited to the preferred embodiment … or to the examples listed within the patent specification." *Glaxo Wellcome, Inc. v. Andrx Pharms., Inc.*, 344 F.3d 1226, 1233 (2003). Moreover, "[w]hen a claim term has an accepted scientific meaning, that meaning is generally not subject to restriction to the specific examples in the specification." *Id.*

b) The file history does not support defendants' construction

Defendants' citations to the file history are equally unconvincing. ***First,*** defendants point to a rejection during prosecution of the '020 patent, where the examiner asserted that the prior art '241 patent taught amorphous vilazodone and pending claims encompassed amorphous vilazodone as well. *See* '020 File History, 12/18/2009 Non-Final Rejection at 5; Def. Br. 9.[3] In response, the patentees canceled two claims and amended a third by deleting amorphous vilazodone, thereby limiting the proposed claims to non-amorphous (that is, crystalline) forms. '020 File History, 3/18/2010 Remarks at 10. But this amendment does not offer any guidance as to the meaning of the term "crystalline" itself. Defendants do not explain how this action by the patentees supports their position, nor can they.

Second, defendants cite a statement by the examiner that the prior art '241 patent "fails to teach or suggest a crystalline form of [vilazodone]" and "fails to anticipate or render obvious claims reciting specific crystalline forms of [vilazodone]." '195 File History, 8/17/2011 Non-Final Rejection at 13-14; Def. Br. 10. Again, defendants do not explain how this language supports their construction of "crystalline." If anything, the statement that the prior art '241

[3] Defendants cite incorrect prosecution history dates throughout their opening brief. *See, e.g.*, Def. Br. 9 (referring to 12/18/2009 Non-Final Rejection as dated 4/28/2008); Def. Br. 10 (referring to 8/17/2011 Non-Final Rejection as dated 11/12/2010, and referring to 11/18/2011 Non-Final Rejection as dated 5/4/2011). Rather than noting each error, plaintiffs simply cite the correct dates in this brief.

patent fails to teach or suggest "***a*** crystalline form" of vilazodone suggests that the '241 patent does not teach ***any*** crystalline form of vilazodone. Notably, the '195 patent includes claims broadly drawn to crystalline forms ('195 patent, claim 1) as well as to anhydrates and hydrates ('195 patent, claims 3-7) that are not limited to specific crystalline forms. Moreover, it is unsurprising that the examiner referred to "claims reciting specific crystalline forms," since certain pending claims did in fact recite specific crystalline forms of vilazodone. *See* '195 File History, 8/17/2011 Non-Final Rejection at 13-14; pending claims shown in Preliminary Amendment filed 11/12/2010 at 2-4. But again, nothing in these statements or actions suggests that the unmodified term "crystalline" is limited only to the disclosed embodiments in the patents-in-suit.

Third, defendants point to a rejection during prosecution of the '804 patent, in which the examiner asserted that the '241 patent teaches a method of using vilazodone in crystalline form. '804 File History, 11/18/2011 Non-Final Rejection at 5-6; Def Br. 10. While amending the pending claims to recite expressly crystalline modification IV, the patentees explicitly stated that they were not "acquiescing in the [examiner's] characterization"; that the amendments were "made to expedite prosecution of the present application"; and that they reserved "the option to further prosecute the same or similar claims in the present or another patent application." '804 File History, 2/9/2012 Remarks at 3-4. Accordingly, there was no clear disavowal; indeed, there was the opposite. Even had there been such a disavowal (despite the patentees' explicit statements to the contrary), it would at most be limited only to the claims of the '804 patent and to Form IV. That the patentees went on to prosecute and obtain subsequently many additional claims in other applications not limited to Form IV, however, further emphasizes there was no disavowal here.

Defendants similarly cite the patentees' statement during prosecution of the '804 patent that "the [prior art] '241 patent fails to teach or suggest the polymorphic form IV set forth in the amended claims." *Id.* at 4. It is unsurprising that the patentees focused on form IV in this response, because the claims under discussion had been amended to recite that form. Contrary to defendants' arguments, however, there is no basis to interpret the statement that the '241 patent ***does not disclose*** Form IV as some kind of an admission that the '241 patent ***does disclose*** any other crystalline form. To the contrary, as discussed above, the examiner's statement that the '241 patent "fails to teach or suggest a crystalline form of [vilazodone]" during the prosecution leading to the '195 patent evidences that the '241 patent did not teach ***any*** crystalline form.

Finally, defendants point to the notice of allowability in the file history of the '921 patent, in which the examiner stated that the prior art '241 patent "does not teach the claimed crystalline forms" and "lacks identical or obvious crystalline forms of vilazodone." '921 File History, 12/13/2013 Notice of Allowability at 2; Def. Br. 11. This is not a statement that the asserted claims are limited to specific crystalline forms, nor can it be so interpreted. The claimed crystalline forms include those of claim 1 of the '921 patent ("an anhydrate, hydrate, solvate or dihydrochloride"). This claim is not limited to any specific form, but rather to classes of crystalline form. It is also unsurprising that the examiner referred to "identical" crystalline forms, as the allowed claims also include a number of other claims directed to specific forms. *See, e.g.*, '921 patent, claim 2 (directed to an "anhydrate in crystalline modification III").

In sum, nothing in the prosecution history cited by defendants requires construing the term "crystalline" in any way other than its plain and ordinary meaning.

* * *

Because "crystalline" has a well-understood meaning to a POSA that is consistent with the intrinsic record, it need not be construed. To the extent that the Court interprets the term, it should be accorded that plain and ordinary meaning, and the term "crystalline modification" should be construed as "crystalline form."

B. "Exhibits the following XRD data"

Claim Term	Patent/claim	Plaintiffs' Proposed Construction	Defendants' Proposed Construction
"exhibits the following XRD data"	'020 patent, claim 1	Displays X-ray diffraction pattern consistent with the following values, with experimental error ranges (*e.g.*, +/- 0.1^{o} for two-theta values)	Must show all the following peaks and intensities

A POSA would understand that the claim language "exhibits the following XRD data" incorporates experimental error ranges. This common sense notion is confirmed by the prosecution history of the '020 patent, in which the applicant explicitly incorporated the experimental error range from Table III of the specification into the claims by reference. *See* Pl. Br. 11; '020 File History, 3/18/2010 Amendment after Non-Final Rejection at 8. A POSA would know that scientific data is essentially ***always*** accompanied by error ranges. *See* Pl. Br. 11-12; Bernstein Decl. ¶¶ 42-43.

Defendants nonetheless argue that no experimental error ranges should apply, pointing to the patentees' claim amendment to add "approximately" before "the following XRD data," and the withdrawal of this amendment a few weeks later. *See* '020 File History, 8/18/2010 Amendment Under 37 C.F.R. 1.312 at 1-6; *id.* at 9/14/2010 Withdrawal of Amendment Under 37 C.F.R. 1.312. But there is no basis for interpreting an amendment relating to the general hedge word "approximately" as an intention to disclaim experimental error. Moreover, neither the

amendment nor the withdrawal were prompted by a rejection, and neither led to allowance of the claims; instead, both the amendment and withdrawal occurred ***after*** the notice of allowance had issued. In addition, the withdrawal explicitly states that it is made "without prejudice or disclaimer." *See* '020 File History, 9/14/2010 Withdrawal of Amendment Under 37 C.F.R. 1.312. There is thus no basis to intuit disavowal of experimental error ranges based on this portion of the prosecution history.

Defendants also point to the patentees' amendment of the claim to add "exhibits the following XRD data" and accompanying data, Def. Br. 12-13, but fail to explain why this amendment supports their position at all. That the patentees added XRD data ***raises*** the claim construction issue now disputed—which relates to whether the data incorporates experimental error—but does not resolve it.

Next, defendants point to language in a double patenting rejection during prosecution of the '804 patent, in which the examiner stated that the "characteristic XRD peaks" claimed in the'804 patent "are exactly the same XRD peaks depicted in claim 1 of the '020 Patent." *See* '804 File History, 03/27/2012 Final Rejection at 6. There is no dispute that the two-theta values in claim 1 of the '804 patent match those in claim 1 of the '020 patent, but again, defendants fail to explain why this suggests disavowal of experimental error ranges. On the contrary, because claim 1 of the '804 patent contains explicit error ranges of ±0.1, *see infra* at 11-12, the examiner's statement at most indicates that those same error ranges apply to the '020 patent, supporting ***plaintiffs'*** position here.

The record is clear that "exhibits the following XRD data" incorporates commonly understood error ranges.

C. "Corresponding to"

Claim Term	Patent/claim	Plaintiffs' Proposed Construction	Defendants' Proposed Construction
"corresponding to"	'804 patent, claims 1-3	Plain meaning/no construction required	Matching the precise values recited in the claims

As discussed in plaintiffs' opening brief, "corresponding to" is a straightforward term meaning simply "consistent with," and requires no construction by this Court. *See* Pl. Br. 13.

Defendants, however, make the surprising assertion that "consistent with" has a broader meaning than that of "corresponding to," Def. Br. 15, but they never explain why that is so. Instead, defendants premise their argument on the flawed logic that "corresponding to" in the claims requires "matching the precise values recited in the claim," despite the fact that the claims of the '804 patent include explicit error margins. *See* '804 patent col. 28, ll. 3-5, 10-11, and 14-15. These error margins—which defendants never even mention in their opening brief—make clear that precise values are ***not*** required by the claims, and that defendants' proffered construction therefore cannot be correct. As with the claim term "exhibits the following XRD values," discussed *supra* at 9-11, defendants' position is contradicted by the understanding of a POSA that experimental error ranges almost always apply to scientific data. Pl. Br. 13; Bernstein Decl. ¶¶ 46-47.

Defendants rely upon the prosecution history of the parent application to the '804 patent, in which the examiner rejected "approximately" as indefinite, and the patentees responded by replacing "approximately" with "corresponding to" in order to "expedite prosecution." *See* File History of U.S. Application No. 12/566,835, 10/21/2010 Final Rejection at 2-3; *id.* at 2/8/2011 Response to Final Office Action at 2. Defendants assert that this removal of "approximately" supports their construction, but fail to acknowledge that in the same response, the patentees

reported that the examiner had agreed during an interview to recitation of the term "±0.1 degrees" in the claims. *Id.* at 2/8/2011 Response to Final Office Action at 2-3 and 5-6. The examiner allowed the claims with the explicit ±0.1 degree error margin included. Thus, the amendments cited by defendants did not "limit[] the claim scope to peaks 'matching the precise values recited in the claims.'" Def. Br. 17. Indeed, they indicate the opposite.[4]

D. "Characteristic peak"

Claim Term	Patent/claim	Plaintiffs' Proposed Construction	Defendants' Proposed Construction
"characteristic peak"	'804 patent, claims 1-3	Peak representative of a crystalline form's X-ray diffraction pattern	A powder XRD peak having intensity ≥ 3*noise, which serves to identify the crystalline modification

"Characteristic peak" in the claims of the '804 patent simply refers to a peak representative of a crystalline form's X-ray diffraction pattern, and does not require—as defendants assert—a minimum intensity of 3*noise. Pl. Br. 14-15; Bernstein Decl. ¶¶ 49-52.

Defendants argue that this minimum intensity should be read into the claims because Table III in the '804 patent lists data for ten "characteristic peaks" for each of the listed forms except for Form XIV, as to which it lists data for only seven "characteristic peaks" because "[f]urther peaks exhibit intensities <3* noise." Def. Br. 17-18; '804 patent col. 27, l. 11. But this does not imply or require that the claimed characteristic peaks must have intensity greater than or

[4] Defendants also assert that plaintiffs' proposed construction of "corresponding to" is "akin to construing 'corresponding to' to mean 'about' or 'approximately,'" and would therefore be indefinite. Def. Br. 16. But defendants cite no support for this conclusion. Plaintiffs have never suggested that the term "corresponding to" is equivalent to "about" or "approximately." And, in any event, "approximately" is not indefinite; it is a commonly used term of degree in patents. *See, e.g.*, *Bristol-Myers Squibb Co. v. Apotex, Inc.*, C.A. No. 10-5810, 2013 WL 1314733, *23-24, *26-27 (D.N.J. Mar. 28, 2013) (rejecting defendant's argument that "approximately" was indefinite).

equal to 3* noise. Rather, to the contrary, it makes clear that characteristic peaks ***may have intensities less than 3* noise*** but are simply not listed in Table III. Had the patentees intended to limit the claims to characteristic peaks with intensities greater than or equal to 3* noise, they could have done so—but they did not.

A POSA understands that a "characteristic peak" is simply a peak used to identify a particular crystalline form, and does not have a specific intensity requirement. Bernstein Decl. ¶¶ 49-50. Indeed, a POSA can reliably identify a crystalline form based on peaks with intensities less than 3* noise, so such a threshold intensity requirement would not make sense. *Id.* ¶ 51. Defendants do not address the perspective of a POSA regarding "characteristic peak" at all in their opening brief. Their proposed construction of this term should be rejected.

E. "Effective amount"

Claim Term	Patent/claim	Plaintiffs' Proposed Construction	Defendants' Proposed Construction
"effective amount"	'804 patent, claim 1 '195 patent, claims 1-2 '921 patent, claims 13-14	Amount sufficient to promote a therapeutic effect	An amount of the specified crystalline modification of vilazodone HCl sufficient to produce the desired effect

As discussed in plaintiffs' opening brief, Pl. Br. 15-17, an "effective amount" is an amount "sufficient to promote a therapeutic effect." Defendants' proposal that an "effective amount" must be "sufficient to produce the desired effect" cannot be reconciled with medical reality. Virtually no medicine is effective all of the time or in all patients, and antidepressants in particular are well known to affect different patients differently. Pl. Br. 16-17; Thase Decl. ¶ 40. Moreover, some drug products or regimens include more than one component, each of which ***promotes*** the desired effect but does not necessarily ***produce*** the desired effect on its own.

Plaintiffs' proposed construction is consistent with these medical facts, while defendants' proposed construction is not.

Defendants cite *Abbott Laboratories v. Baxter Pharmaceutical Products, Inc.*, 334 F.3d 1274 (Fed. Cir. 2003), in support of their construction, but *Abbott* is inapposite. The claims in that patent did not concern methods of treatment, but rather related to the use of an effective amount of a Lewis acid inhibitor to prevent degradation of sevoflurane, an anesthetic, to protect its shelf life. *Id.* at 1276-78. Any discussion of the ordinary use of the words "effective amount" must apply to the particular context in which they are used.[5] Moreover, although defendants argue that *Abbott* held that "the customary usage of an 'effective amount' means an amount of recited substance sufficient to produce the desired effect," Def. Br. 5, *Abbott* contains no such holding—indeed, a "desired effect" is never mentioned in *Abbott*. *Abbott* construed "effective amount" as it did because it was consistent with the specification, and because there was no clear disavowal by the patent applicant, *see* 334 F.3d at 1277-80. *Abbott* thus provides no support for defining the term "an effective amount" in the context of the methods of treatment described and claimed in the patents-at-issue.

Defendants also point to references to "treating" in the specification and claims of the patents-in-suit, and note that the parties stipulated that "treating" means "attempting to cause a therapeutic effect on." Def. Br. 5-6. Defendants conclude from this stipulated definition that an "effective amount" must be sufficient to "cause a desired effect." Def. Br. 5-6. But defendants simply ignore the words ***"attempting to cause"*** in the stipulated definition of "treating." As both

[5] Indeed, the Federal Circuit expressly relied on this context, stating: "At a minimum, the '176 patent provides support for defining an 'effective amount' of inhibitor to be the amount of Lewis acid inhibitor needed to stabilize sevoflurane housed in a particular glass vessel under a given set of environmental conditions. Thus, the specification supports the concept that the amount of Lewis acid inhibitor depends on many environmental considerations." *Abbott*, 334 F.3d at 1278.

parties recognized by stipulating to this definition, treating does not require ***causing*** a therapeutic effect, but only ***attempting*** to cause it. That distinction is critical and supports plaintiffs' proposed construction of "effective amount."

In addition, defendants argue that plaintiffs' proposed definition "leads to illogical results" because it "rewrite[s]" the claim to require only "a trace" of the infringing substance. Def. Br. 6. That is not correct. Plaintiffs—like defendants—propose a construction of "effective amount" based on function, not specified quantity. Whether a particular amount is an "effective amount" under plaintiffs' construction will depend on the factual question of whether it is an amount "sufficient to promote a therapeutic effect." That issue will be part of the infringement analysis and may be the subject of expert testimony.

Lastly, as discussed in plaintiffs' opening brief, the phrase "the specified crystalline modification of vilazodone HCl" in defendants' proposed construction of "effective amount" should be rejected because it is redundant: each of the claims at issue identifies what substance must be present in an "effective amount." Pl. Br. 15-16.

Plaintiffs' construction of "effective amount" should be adopted.

F. "Administer" / "Administered" / "Administering"

Claim Term	Patent/claim	Plaintiffs' Proposed Construction	Defendants' Proposed Construction
"administer" "administered" "administering"	'020 patent, claim 2 '195 patent, claims 1-2 '804 patent, claim 1 '921 patent, claims 10, 12-14	Plain meaning/no construction required	Deliver[ed/ing] into the body

"Administer" is a straightforward term that simply refers to providing a patient a drug or treatment for a therapeutic purpose, and is not narrowly limited to delivery "into" the body. Pl. Br. 18-19; Thase Decl. ¶ 48.

Defendants defend their construction with a straw man, arguing that plaintiffs' argument for plain meaning "encompass[es] the scenario in which a composition containing a pharmaceutical compound is handed or prescribed to a patient suffering from a disorder, but is never taken by the patient and therefore never enters into the body." Def. Br. 4. But plaintiffs have never argued that treatment may occur if the treating composition never reaches the patient's body—clearly the purpose of administering a treatment for a therapeutic purpose is that the patient receive the drug.

Defendants' construction is too narrow, however, because it limits "administer" solely to the ***actual insertion*** of the medication into a patient's body. Nothing in the record—including the reference to "forms of administration" in the specification, cited by defendants, Def. Br. 3 (citing '804 patent, col. 15, ll. 29-32)—requires such a limitation. Nor does anything in the record require deviation from the plain meaning of "administer," which encompasses a doctor prescribing the medication to the patient as well as actual ingestion. Pl. Br. 18-19; Thase Decl. ¶ 48.

Defendants cite *Andrulis Pharmaceuticals Corp. v. Celgene Corp.*, C.A. No. 13-1644-RGA, 2015 WL 3978578 (D. Del. June 26, 2015), but "a particular term used in one patent need not have the same meaning when used in an entirely separate patent." *Medrad, Inc. v. MRI Devices Corp.*, 401 F.3d 1313, 1318 (Fed. Cir. 2005). Indeed, a number of other district courts have ruled differently. In *Pozen Inc. v. Par Pharmaceutical, Inc.*, 719 F. Supp. 2d 718, 724-25 (E.D. Tex. 2010), for example, the court "decline[d] to narrow the meaning" of "administering"

by adopting defendants' proposed construction of "putting into a patient," and instead adopted a plain meaning construction. The court noted that this plain meaning of "administering" could be reflected by the phrase "to mete out," and "would include giving a patient a drug in any normal manner," such as "providing a tablet to a patient under circumstances where it is reasonable to believe that a patient is going to take the tablet." *Id.* at 725; *see also Prometheus Labs. Inc. v. Roxane Labs., Inc.*, No. 11-230, 2013 WL 5333033, at*4 (D.N.J. Sept. 23, 2013) (adopting "ordinary meaning of 'administering'" and noting that "administering" is "not limited to solely 'applying onto or into' a patient, but also includes 'to mete out,' 'to give,' 'to make application of,' 'to supervise the formal taking of,' and 'to bring into use or operation'"); *Smith Kline & French Labs., Ltd. v. Teva Pharms. U.S.A., Inc.*, C.A. No. 05-197-GMS, 2006 WL 6130327 (D. Del. Mar. 1, 2006) (construing "administering" as "giving a therapeutic agent to a subject to be treated," based on stipulation of the parties).

The meaning of "administer" is clear and the term requires no construction. If construed, a construction of "providing a patient a drug or treatment for a therapeutic purpose" is appropriate. *See* Thase Decl. ¶ 48.

G. Preamble

Claim Term	Patent/claim	Plaintiffs' Proposed Construction	Defendants' Proposed Construction
"A method of treating a patient suffering from a depressive disorder, an anxiety disorder, a bipolar disorder, mania, dementia, a substance-related disorder, a sexual dysfunction, an eating disorder, obesity, fibromyalgia, a sleeping disorder, a psychiatric disorder, cerebral infarct, tension, side-effects in the treatment of hypertension, a cerebral disorder, chronic pain, acromegaly, hypogonadism, secondary amenorrhea, premenstrual syndrome, undesired puerperal lactation, or combinations thereof"	'020 patent, claim 2 '921 patent, claims 10, 12 -14	Entire preamble is limiting	"A method of treating," is not limiting

As discussed in plaintiffs' opening brief, the phrase "a method of treating" in the preamble of the '020 patent, claim 2, and the '921 patent, claims 10 and 12-14, is limiting because it is critical to understanding the claimed invention. *See* Pl. Br. 19-20.

Defendants argue that "a method of treating" is not limiting because it is a statement of purpose. Def. Br. 19-20. But that does not end the inquiry; preamble language describing a purpose may be limiting if it is fundamental to the invention. *See, e.g.*, *Vizio, Inc. v. ITC*, 605 F.3d 1330, 1340-41 (Fed. Cir. 2010) ("for decoding" language in preamble is limiting because "'decoding' is the essence or a fundamental characteristic of the claimed invention" and the claimed apparatus "would have little meaning without the intended objective of decoding"); *Griffin v. Bertina*, 285 F.3d 1029, 1033 (Fed. Cir. 2002) (preamble language "for diagnosing an increased risk of thrombosis or a genetic defect causing thrombosis" is limiting because

"[d]iagnosis is … the essence of this invention; its appearance in the count gives 'life and meaning' to the manipulative steps"). Here, reference to administering a compound is meaningless in the abstract, without the context of treatment. *See Griffin*, 285 F.3d at 1033 ("In the absence of the preamble's stated objective to diagnose thrombosis, the term 'test subject' [in the first claimed step] is empty language. What is one testing for, and who is a suitable subject?"). Moreover, "method of treatment" distinguishes the objective of the invention from other possible objectives of administering medicine, such as prevention. *See* Pl. Br. 19-20.

TomTom, Inc. v. Adolph, 790 F.3d 1315 (Fed. Cir. 2015), cited by defendants, does not require a different result. Although *TomTom* held that the preamble language stating a purpose in that case was not limiting, it did not hold that such preamble language can ***never*** be limiting. Indeed, *TomTom* is clear that whether a preamble is limiting "'is determined on the facts of each case in light of the claim as a whole and the invention described in the patent.'" *Id.* at 1323 (citation omitted). Based on the specific claim language in *TomTom*, the Court found that the preamble did "not recite essential structure or steps, or give necessary life, meaning, and vitality to the claim." *Id.* at 1324. That fact-specific conclusion does not compel the same conclusion here, where the opposite is true, for the reasons stated in plaintiffs' opening brief. *See* Pl. Br. 19-20.

III. CONCLUSION

For the reasons set forth in plaintiffs' opening brief and herein, plaintiffs' proposed constructions should be adopted.

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July 27, 2016

CERTIFICATE OF SERVICE

I hereby certify that on July 27, 2016, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on July 27, 2016, upon the following in the manner indicated:

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